

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

ESSENTIAL PHARMACEUTICALS, LLC

Plaintiff,

CIVIL ACTION NO. \_\_\_\_\_

v.

DEMAND FOR JURY TRIAL

LIFEBLOOD MEDICAL, INC.,

Defendant.

**COMPLAINT**

Plaintiff, ESSENTIAL PHARMACEUTICALS, LLC (“Essential”), for its complaint against Defendant LIFEBLOOD MEDICAL, INC. (“Lifeblood”), alleges as follows:

**NATURE OF THE CASE**

1. This is an action seeking a declaratory judgment that Essential has not infringed any claims of U.S. Patent No. 7,220,538 (the “’538 patent”), declaratory judgment that Essential has not breached a License and Supply Agreement with Lifeblood (the “Agreement”), and damages for Lifeblood’s breach of the Agreement. A copy of the ’538 patent is attached hereto as Exhibit A.

2. An actual controversy has arisen and now exists between Essential and Lifeblood concerning their respective rights and duties under the Agreement and the ’538 patent in that Lifeblood has breached its obligations under the Agreement, and Lifeblood contends Essential’s current conduct is in breach of the Agreement and will infringe one or more claims of the ’538 patent.

3. Essential seeks damages for Lifeblood's breach of the Agreement, and Essential further desires a judicial determination of its rights and duties and a declaration as to whether it has breached the Agreement or infringed any claims of the '538 patent.

#### **THE PARTIES**

4. Essential is a Delaware limited liability company with its principal place of business at 770 Newtown-Yardley Road, Suite 212, Newtown, Pennsylvania.

5. Upon information and belief, Lifeblood is a New Jersey corporation with its principal place of business at 83 South Street, Suite 101, Freehold, New Jersey.

#### **JURISDICTION AND VENUE**

6. This Court has personal jurisdiction over Lifeblood because it transacts business in and has contracted to supply services or things in the Commonwealth of Pennsylvania, including entering the Agreement with Essential, and Lifeblood derives substantial revenue from its activities in the Commonwealth of Pennsylvania.

7. This Court has subject matter jurisdiction over Counts I and II under 28 U.S.C. §§ 1331 and 1338(a) and has supplemental jurisdiction over Count III under 28 U.S.C. § 1367(a).

8. This Court has authority to grant declaratory relief under 28 U.S.C. § 2201 and § 2202.

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

#### **FACTUAL BACKGROUND**

10. Lifeblood's LiferCell product is a serum and animal protein free solution intended to be used, among other purposes, as a substitute for fetal bovine serum and as a cryopreservative.

11. Under the Agreement, entered on September 8, 2010, Lifeblood granted to Essential an exclusive license to offer for sale, sell, market, distribute, and export Lifeblood's LiforCell products. Lifeblood retained the rights to make, have made, and import the LiforCell products, but Lifeblood agreed it would manufacture the LiforCell products and supply them to Essential. If Lifeblood is ever unable or unwilling to supply Essential's needs for LiforCell products, Lifeblood further agreed to grant to Essential a license to make, have made, and import LiforCell products.

12. After entering the Agreement, Essential intended to introduce three serum and animal protein free products based on Lifeblood's LiforCell product: Cell-Ess, Cryo-Ess, and Clin-Ess (collectively, the "Essential Products"). The Cell-Ess product is to be a substitute for fetal bovine serum; the Cryo-Ess product is to be a cryopreservative; and the Clin-Ess product is to be a transportation medium for tissues and cells.

13. Before entering the Agreement, Lifeblood represented to Essential that its LiforCell product was merchantable and fit for these three purposes.

14. After entering the Agreement, Essential learned that the LiforCell product does not work as a substitute for fetal bovine serum or as a cryopreservative, which meant that LiforCell could not be used for Essential's anticipated Cell-Ess or Cryo-Ess products. Essential financed substantial research and development to modify the LiforCell product, but cannot make it work as a replacement for fetal bovine serum or as a cryopreservative.

15. Accordingly, Essential ultimately incurred substantial expense to develop its own serum and animal protein free solution (the "Essential Formula") that it could use for all of the Essential Products.

16. After Lifeblood learned in January 2013 that Essential intended to manufacture the Essential Products using the Essential Formula with a manufacturer other than Lifeblood, Lifeblood informed Essential that its manufacture of the Essential Products with a manufacturer other than Lifeblood would be a breach of the Agreement and would constitute infringement of the '538 patent.

17. The Agreement is governed by the laws of the State of Delaware.

**COUNT I**  
**Declaratory Judgment of**  
**Noninfringement of the '538 Patent**

18. Essential restates and realleges paragraphs 1 through 17.

19. An actual controversy exists between Essential and Lifeblood as to whether the '538 patent is not infringed by Essential.

20. Because Lifeblood's LiforCell products do not function as a substitute for fetal bovine serum or as a cryopreservative, Essential has developed its own Essential Formula, which functions as a substitute for fetal bovine serum and as a cryopreservative.

21. Essential has made and/or had made its Essential Formula.

22. Lifeblood has informed Essential that its manufacture of the Essential Formula infringes the '538 patent. In a January 22, 2013 letter from Lifeblood to Essential, Joseph Fischer, Lifeblood's president and CEO, explained that the Essential Formula "could not have been created without utilizing the patented knowledge that is contained in Lifeblood Medical Patent for LiforCell [*i.e.*, the '538 patent]." (Exh. C.)

23. Further, during a meeting with Essential on February 27, 2013, Mr. Fischer threatened that Essential's manufacture of the Essential Formula infringes the '538 patent.

24. A judicial declaration is necessary and appropriate so that Essential may ascertain its rights as to whether it infringes the '538 patent.

25. Essential does not infringe the '538 patent directly, contributorily, or by inducement because its Essential Formula does not practice any of the claims of the '538 patent.

26. Essential requests that the Court enter a declaratory judgment that Essential has not and does not infringe any claim of the '538 patent.

**COUNT II**  
**Declaratory Judgment That Essential**  
**Has Not Breached the Agreement**

27. Essential restates and realleges paragraphs 1 through 26.

28. An actual controversy has arisen and now exists between Essential and Lifeblood concerning their respective rights and duties under the Agreement. Lifeblood contends that Essential must manufacture the Essential Products exclusively with Lifeblood, and that Essential will breach the Agreement if it retains another manufacturer to manufacture any of the Essential Products although Essential intends to use the Essential Formula, which Lifeblood does not own or control under the Agreement.

29. The Essential Formula is not a "Product" covered by the Agreement because it is not owned or controlled by Lifeblood, does not have the same chemical composition as any product Lifeblood has ever manufactured or sold under the LiforCell trademark, and is not covered by any of the patents licensed under the Agreement. Compared to LiforCell, the Essential Formula includes different ingredients (and omits many others) to make it work as a substitute for fetal bovine serum and as a cryopreservative, which LiforCell is not capable of doing.

30. Moreover, under the Agreement, Lifeblood represented and warranted that "the Licensed Patent Rights [*i.e.*, the '538 patent] cover the Product." Because the '538 patent does not cover the Essential Formula, that formula is not a Product under the Agreement.

31. Essential desires a judicial determination of its rights and duties, and a declaration that it is not required under the Agreement to use Lifeblood to manufacture any of the Essential Products using the Essential Formula.

32. Essential has given Lifeblood notice that it intends to pursue other manufacturers for its Essential Products. (Exh. B.)

33. Lifeblood's president and CEO, Joseph Fischer, sent a January 22, 2013 letter to Allan Weber, Essential's CEO, asserting that Essential's "statement of pursuing other manufacturing options is currently in violation of the Agreement." (Exh. C ¶ 2.)

34. This statement from Lifeblood to Essential confirms there is an actual controversy between Essential and Lifeblood regarding whether Essential is required under the Agreement to retain Lifeblood to manufacture the Essential Products using the Essential Formula.

35. The Court has jurisdiction over this declaratory judgment claim under 28 U.S.C. § 1338(a) because it necessarily raises a federal issue, actually disputed and substantial, in that it will require the Court to determine the scope of the '538 patent to determine whether the Essential Formula is a "Product" covered under the Agreement. "Product" is defined as "any serum and animal protein free solution and/or cell culture medium *owned or controlled* by Lifeblood." A "Product" is further defined as any product "having modified chemical compositions as speculated in the Licensed Patent Rights [*i.e.*, the '583 patent]." Finally, under the Agreement, Lifeblood represented and warranted that "the Licensed Patent Rights [*i.e.*, the '583 patent] cover the Product." Therefore, to determine whether the Essential Formula is a "Product" under the Agreement, the Court will necessarily have to decide whether the Essential Formula is covered by the scope of the '538 patent, an issue of federal law.

36. Essential requests that the Court enter a declaratory judgment that it is not required under the Agreement to retain Lifeblood to manufacture the Essential Products using the Essential Formula and that Essential may retain other manufacturers and is not required to pay any royalties to Lifeblood for products manufactured by other manufacturers.

**COUNT III**  
**Breach of Contract**

37. Essential restates and realleges paragraphs 1 through 36.

38. The Agreement is a valid and enforceable contract between Essential and Lifeblood.

39. In the Agreement, Lifeblood represented and warranted to Essential that Lifeblood's LiferCell products are "merchantable" and "fit for their intended purposes." The LiferCell products are serum and animal protein free solutions intended to be used, among other purposes, as a substitute for fetal bovine serum and as a cryopreservative.

40. The LiferCell products do not work as a substitute for fetal bovine serum or as a cryopreservative. Among other problems, the nanoliposomes used in Lifeblood's product do not have a high enough fat content, the growth factors in Lifeblood's solution are unstable and sub-therapeutic, and the cryopreservative in Lifeblood's product is toxic to cells.

41. Therefore, Lifeblood breached the Agreement because it represented and warranted that its LiferCell products work as a substitute for fetal bovine serum and as a cryopreservative.

42. Under the Agreement, Essential paid \$500,000 to Lifeblood for rights in the LiferCell products, expressly relying on Lifeblood's representations and warranties.

43. Because the LiferCell products do not function as a substitute for fetal bovine serum or as a cryopreservative, Essential has incurred over \$500,000 in expenses over the past

two years unsuccessfully trying to modify the LiferCell product to function for those purposes and ultimately developing the Essential Formula.

44. Accordingly, Essential requests that the Court enter judgment awarding it damages in the amount of at least \$1,000,000 to compensate it for Lifeblood's breach of the Agreement.

#### **PRAYER FOR RELIEF**

WHEREFORE, Essential respectfully requests that the Court enter judgment:

- a. in favor of Essential and against Lifeblood on all of Essential's claims;
  - b. finding Lifeblood has breached the Agreement with Essential;
  - c. declaring that Essential has not breached the Agreement with Lifeblood;
  - d. declaring that Essential has not infringed the '538 patent;
  - e. awarding Essential all actual, incidental, and consequential damages adequate to compensate for Lifeblood's breach of the Agreement together with interest;
  - f. awarding Essential its costs and attorney's fees as permitted under applicable law;
- and,
- g. awarding Essential such other relief as the Court may deem just and proper.

#### **JURY DEMAND**

Under Rule 38(b) of the Federal Rules of Civil Procedure, Essential demands a trial by jury for all claims so triable.



Dated: March 13, 2013

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